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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/584,978      | 06/02/2000  | Dr. Rudi Neirinckx   | 44334               | 5707             |

35928                      7590                      04/01/2004

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT                      PAPER NUMBER

1654

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                        |                               |                                     |  |
|------------------------|-------------------------------|-------------------------------------|--|
| <b>Advisory Action</b> | Application No.<br>09/584,978 | Applicant(s)<br>NEIRINCKX, DR. RUDI |  |
|                        | Examiner<br>Jeffrey E. Russel | Art Unit<br>1654                    |  |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a)  The period for reply expires 4 months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will not be entered because:
- (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
- (b)  they raise the issue of new matter (see Note below);
- (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment.

3.  Applicant's reply has overcome the following rejection(s): See attachment.
4.  Newly proposed or amended claim(s) \_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a)  affidavit, b)  exhibit, or c)  request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a)  will not be entered or b)  will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 11-17.

Claim(s) withdrawn from consideration: 9 and 10.

8.  The drawing correction filed on \_\_\_\_\_ is a)  approved or b)  disapproved by the Examiner.
9.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10.  Other: \_\_\_\_\_

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1. The proposed deletion of the word "sole" from claim 11 raises new issues of obviousness with respect to the European Patent Application 339,905. See the final Office action mailed November 20, 2003, page 9, first full paragraph.
2. The proposed amendments, had they been entered, would have overcome the objection and rejections set forth in paragraphs 3, 4, and 5 of the final Office action mailed November 20, 2003.
3. The proposed amendment to the abstract would not have overcome the objection set forth in paragraph 2 of the final Office action because the proposed new abstract does not recite the use of possible additional ingredients (e.g., anti-inflammatory products and sulfadiazine).
4. The proposed amendment to the specification would not have overcome the objection set forth in paragraph 6 of the final Office action because the specification would still not recite the concentrations recited in claims 15-17 or the claimed optional additional components such as anti-inflammatory products.
5. The copy of the Neirinckx declaration under 37 CFR 1.132 filed March 22, 2004 can not be relied upon to overcome the obviousness rejections set forth in the final Office action because the declaration is not signed. Once a signed copy of the declaration is submitted, the obviousness rejections will be withdrawn because the Neirinckx declaration at paragraph 7 states that "there is no way to predict that a proposed treatment of psoriasis will be successful without an actual clinical trial". In the absence of a reasonable expectation of success, the examiner's argument that it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to apply the Nanney et al article's treatment to human patients can not be supported. This analysis will also hold with respect to the European Patent

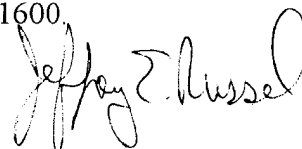
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Application 339,905 and proposed claims 11-16 because the European Patent Application '905 also does not teach treating psoriasis in human patients.

6. Once a signed copy of the Neirinckx declaration is submitted, the proposed amendment filed March 22, 2004 will be entered, the finality of the Office action mailed November 20, 2003 will be withdrawn, and a new grounds of rejection under 35 U.S.C. 112, first paragraph, lack of enablement, will be made against instant claims 11-14. These claims, to the extent that they embrace the administration of EGF in the absence of sulfadiazine, are not enabled by the specification because the specification does not provide any evidence of clinical trials using EGF as the sole active agent, and the Neirinckx declaration will show that there is no expectation of success in the absence of such clinical trials.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel  
Primary Patent Examiner  
Art Unit 1654

JRussel  
March 29, 2004